DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
94353d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

September 19, 2003

Our Reference No. 1000103392

Carl F. Moore, President
Con-Cise Lens Company
14450 Doolittle Drive
San Leandro, CA 94577

WARNING LETTER

Dear Mr. Moore:

During an inspection of Con-Cise Lens Company, located at 14450 Doolittle Drive, San Leandro, CA on June 18 – 24, 2003, our investigator observed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). At that facility, you manufacture and distribute rigid gas permeable contact lenses, which are devices within the meaning of Section 201(h) of the Act.

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of management with executive responsibility to ensure that quality system requirements are effectively established and maintained. [21 CFR 820.20]

2. Failure to control procedures for conducting quality audits and failure to conduct audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22]. Specifically, you have failed to: define the evaluation criteria used to determine whether your quality system is compliant and effective and to document the results of quality audits. For example, your procedure instructs the auditor to determine whether there is a "Quality Assurance System," but does not define what requirements this system must meet. There are no defined requirements in your audit procedure for

management controls, design controls, corrective and preventive actions, document controls, and production and process controls.

3. Failure to document the dates and results of quality system reviews. [21 CFR 820.20(c)]

4. Failure to control procedures to control the design of the device to ensure that specified design requirements are met. [21 CFR 820.30(a)] Specifically, the design process for the Oxycon lens failed to follow established design controls.

5. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. [21 CFR 820.198(a)] Specifically, complaints submitted and entered as a "Credit Memo" that show reports of products failing to conform to their specifications are not entered into the complaint handling system and reviewed and evaluated to determine whether an investigation is necessary.

   Additionally, you are not following your procedure, QSP 198, in that you fail to: use the associated complaint form, enter all of the complaint information into the complaint handling system, identify the device, and to document the results of any evaluation or investigation.

6. Failure to maintain a device master record for the Oxycon Lens. [21 CFR 820.181]

7. Failure to retain all records required to be maintained under 21 CFR Part 820 for a period of time equivalent to the design and expected life of the device, but in no case, less than two years from the date of release for commercial distribution. [21 CFR 820.180(b)] Specifically, you fail to retain the Device History Record [21 CFR 820.184] for the Oxycon lens for the required period of time.

8. Failure to establish and maintain process control procedures that describe the process controls necessary to ensure conformance to specifications. [21 CFR 820.70(a)] Specifically, you have not implemented standard operating procedures (SOPs) and methods that define and control the manner of production. Your SOPs remain in draft form and are not utilized by your production personnel.

9. Failure to document employee training. [21 CFR 820.25(b)] The existing documentation fails to define the training that was given to ensure that the employee will adequately perform his/her assigned responsibilities. In addition, the training records fail to document that the employee has been made aware of any device defects that may occur from the improper performance of his/her specific jobs.

10. Failure to perform and document validation of computer software that is used as part of production [21 CFR 820.70(i)]. Specifically, the software used to control the DAC DLL Series 3 [redacted] has not been validated.

11. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. [21 CFR 820.50] Specifically, you have not established any requirements for two firms that manufacture lenses for you on a contract basis.

12. Failure to establish and maintain schedules for the adjustment, cleaning, and other maintenance of manufacturing equipment and to document maintenance activities. [21 CFR 820.70(g)(l)]. Specifically, you have not established maintenance schedules required for the DAC DLL Series 3 [redacted] Additionally you have failed to adequately document all the maintenance activities performed on the DAC DLL Series 3 [redacted].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the U.S. Food and Drug Administration (FDA).

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We note that seven items on the Form FDA 483 issued on June 24, 2003 were repeat observations from the previous Form FDA 483 issued February 11, 2002. We acknowledge receipt of your written response to the Form FDA 483 dated August 12, 2003. We have completed our review of your response and have determined that your response does not adequately address our concerns. Your response does not contain sufficient documentation of the supporting activities conducted by your firm to correct the deficiencies disclosed during our inspection. We also have two specific comments regarding your response to the Form FDA 483. The Oxycon lens that you manufacture is a Class II device subject to design controls [21 CFR 820.30]. Your response states that design may be addressed through calibration and verification activities. You also state that software validation for the lathe is performed continuously through production verification activities and calibrations. Calibration and manufacturing process verifications are not substitutes for design controls and/or software validation. You also

stated that your firm will maintain in-process manufacturing records for 90 days. Please note that 21 CFR 820.180(b) specifies that all records required to be maintained under 21 CFR Part 820 are to be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition, your response to this Warning Letter should specify the actions taken by management to assure that an adequate quality system for the devices manufactured is established and maintained. Your response should specify when your internal audits were and will be completed. The results of these audits should be reviewed by management with executive responsibility. Please provide documentation of the completion of these management reviews.

Your response to this Warning Letter also should include copies of the updated procedures implemented by your firm, along with associated documentation such as training records and an example of a device history record. Finally, your response should also address the mechanism you have implemented to verify that the corrective actions are effective.

Please direct your response or questions regarding this matter to Russell A. Campbell, Compliance Officer, Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070, tel. (510) 337-6861.

Sincerely,

Dennis K. Linsley
Director
San Francisco District